REMARKS

Claims 1, 3-6 and 8 are pending in the application. Applicant thanks the Examiner for deeming claims 1 and 3-5 to be allowable. Pursuant to a discussion with the Examiner's supervisor, Dr. Remy Yucel on March 15, 2005, claim 6 is amended to improve clarity and to recite that the target cell is a cell *in vitro*. Support for amended claim 6 is found in the published application at least at paragraphs [0012] and [0050]. Upon entry of the above-made amendments, claims 1, 3-6 and 8 will be pending in the application. Applicant reserves the right to prosecute the subject matter of any canceled claims, or any unclaimed subject matter, in a related application.

No new matter has been added by these amendments. Entry of the foregoing amendments and consideration of the following remarks are respectfully requested.

The Rejection Under 35 U.S.C. § 112, First Paragraph, For Lack of Enablement, Should Be Withdrawn

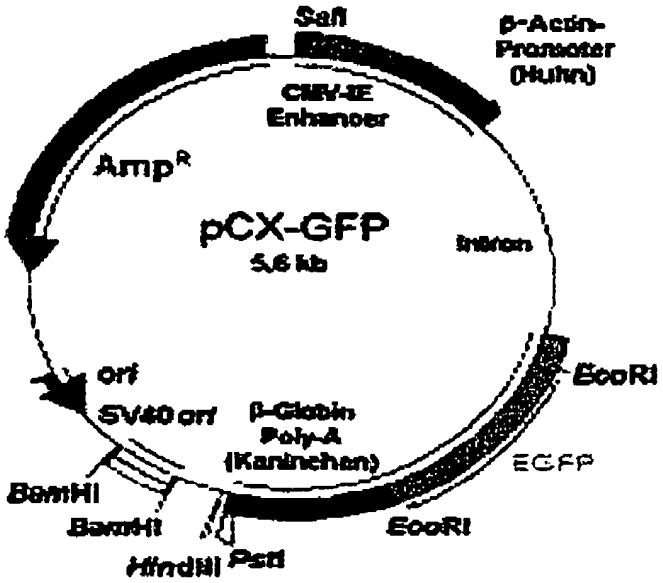
The Examiner has rejected claims 6 and 8 under 35 U.S.C. § 112, first paragraph, as allegedly nonenabled. Applicant traverses as follows.

The use of the peptide vector of the invention, as claimed in amended claim 6 and in claim 8, is enabled because Applicant teaches how to construct specific peptides that mimic viral entry sequences, how to link these peptides to a polynucleotide of interest, how to introduce the peptide vector/polynucleotide combination into target cells, and how to determine whether the polynucleotide of interest has been expressed in a cell or cells *in vitro*. Because the use of the claimed peptide vector is quite simple, and because the state of polynucleotide expression art is very well-developed, a person of skill in the art, reading the specification, would enjoy a reasonable expectation of success in using the peptide vector to transfer and express a polynucleotide *in vitro*.

The Examiner bases nonenablement primarily on three assertions, each implicating gene therapy: (1) that the invention, as exemplified, "does not overcome the problem of gene delivery to targeted cells"; (2) that the invention, as exemplified, "does not solve the problem of transient expression"; and (3) that the experiment described in the Examples "fails to show that the transferred protein was translated so that the desired protein would be expressed at sufficient levels to produce a desired function in the target cells." Office Action at page 3.

Applicant has amended claim 6, and therefrom claim 8, to recite that the target cell is a cell *in vitro*. As such, the issues that arise in the context of gene therapy are not implicated in the claims as amended. The specification, including Examples 1-4, provides enough information such that a person of skill in the art would believe that the transferred polynucleotide, the GFP-encoding sequence, is translated so that the encoded protein would be expressed. As noted above, and as described in the Examples, Applicant detected GFP mRNA in cells that produce no native GFP.

The GFP-encoding sequence used in Example 4, carried by the peptide vector, and expressed in the experimental cells, was obtained from plasmid pCX-GFP, a diagram of which is reproduced below:



The plasmid was digested with *Bam*HI and *Sal*I. As shown above, this *Bam*HI-*Sal*I fragment comprises the GFP-encoding sequence (designated EGFP[1]), a β-actin promoter, the CMV-IE enhancer, and β-globin poly-A sequence. Thus, the polynucleotide used in the Examples of the present specification was designed specifically to express the GFP-encoding sequence in mammalian cells. Given this design, a person of skill in the art would reasonably believe that, as described in Example 4, the GFP-encoding polynucleotide in the peptide vector was expressed and that significant amounts of GFP were produced.

[1] EGFP = Enhanced Green Fluorescent Protein, a version of GFP that produces enhanced fluorescence compared to native GFP.

Moreover, GFP, including EGFP, is one of the most widely-known and accepted experimental markers; *see, e.g.*, Bierhuizen *et al.*, "Enhanced Green Fluorescent Protein as Selectable Marker of Retroviral-Mediated Gene Transfer in Immature Hematopoietic Bone Marrow Cells," *Blood* 90(9):3304-3315 (1997); *see also* Yamanouchi *et al.*, "Identification of Skeletal Muscle Satellite Cells by Transfecting EGFP Driven by Skeletal α-Actin Promoter," *J. Vet. Med. Sci.* 62(11):1213-1216 (2000).

In addition, the art of protein expression from polynucleotides, including the provision of appropriately-oriented promoter, enhancer, and polyadenylation sequences that facilitate expression, was very well-developed at the time of filing. Thus, once a protein coding sequence is introduced into a target cell *in vitro*, the expression of that sequence, and the production of useful quantities of protein, was, at that time, routine to those of skill in the art. A person of skill in the art, therefore, could easily and routinely modify the peptide vector described in the specification to enable the expression of a wide variety of protein-coding sequences. A person of skill in the art, therefore, having the specification and knowledge of gene expression technology in hand, would, at the time of filing, have enjoyed a reasonable expectation of success in using the peptide vector to transfer a polynucleotide to cells *in vitro*, and in having the polynucleotide expressed in those cells.

Applicant therefore respectfully submits that the specification enables claims 6 and 8, as amended. Applicant therefore respectfully requests that the Examiner withdraw the rejection of claim 6 and 8 on this basis.

CONCLUSION

Applicant respectfully requests entry of the foregoing remarks into the file of the above-identified application. Applicant believes that all the pending claims are in condition for allowance. Withdrawal of the Examiner's rejections and allowance of the application are respectfully requested.

Respectfully submitted,

Date: March 15, 2006

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